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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/890,888      | 08/07/2001  | Thomas H. Barrows    | 016230-9004         | 9201             |

23510 7590 03/18/2004

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EXAMINER

GHALI, ISIS A D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/890,888             | BARROWS, THOMAS H.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Isis Ghali             | 1615                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-22 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 11-15-22 is/are rejected.
- 7) ☒ Claim(s) 7-10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The receipt is acknowledged of applicant's request for extension of time, request for continued examination under 1.114, declaration and amendment, all filed 01/02/2004.

Claims 2, 23-36 have been cancelled. Claims 1, 3-22 and 37 are included in the prosecution.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/02/2004 has been entered.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "polymer solvent" in the first line of the claim.

There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 5, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,545,208 ('208).

The present claim 1 reads as elongated structure comprising metal core and porous coating.

US '208 disclosed prosthesis for control delivery of drugs at the site of implantation (abstract; col.1, lines 63-65). The prosthesis comprises a filamentary metal core and a drug carrying bioabsorbable porous polymer coating that overlays at least a portion of the metal (col.2, lines 15-17, 28-30, 56-59; col.6, lines 57-63; col.7, lines 33-36). The bioabsorbable polymer includes poly-L-lactic acid/polyglycolic acid and polyanhydride (col.7, lines 59-64). The drugs include growth factor (col.2, line 23). The

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drugs are impregnated into the polymer layer, and that reads on coating and embedding as claimed in claims 12-14 (col.7, lines 20-23).

The limitation of claims 1, 4, 5, 11-14 are met by US '208.

6. Claims 16, 17, 20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,486,593 ('593).

US '593 disclosed bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The fibers can also comprise titanium, metal alloys such as chromium, cobalt, and molybdenum (col.19, lines 40-45). The fibers of the invention are formed by melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48; col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26). The polymer solvent is inherently pore solving agent.

The limitations of the above claims are met by the reference.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 3 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '208 in view of US 2004/0039438 ('438).

The teachings of US '208 are discussed above. The reference does not teach the material of the metal core or the pore sizes.

Regarding the pore size, this does not impart patentability to claims, absent evidence to the contrary.

US '438 disclosed a stent comprising metal layer and porous layer (abstract; page 1, 0010). The metal core is made of metals that allow visibility of the stent when implanted in the body and includes nickel, stainless steel, chromium, titanium, or alloys thereof (page 2, 0013, 0014).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an elongated structure of metal core and polymeric porous coating as disclosed by US '208, and select one of the metals disclosed by US '438, motivated by US '438 that these metals allow visibility of the stent when implanted in the body, with reasonable expectation of having structure comprising metal core and porous polymer coating that allows the follow up.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '208 in view of US 2002/0049426 ('426).

The teachings of US '208 are discussed above. However, the reference does not teach the active agent to be delivered are cells.

US '426 teaches the cylinder apparatus to be implanted in the body to deliver active agents including cells embedded in a polymeric material and allows the implantation of artificial organs (abstract; page 4, 0042-0044; page 10, 0083).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide an elongated structure comprising metal core and porous polymeric sheath that deliver active agent to the implantation site as disclosed by US '208, and select cells to be delivered by the structure as disclosed by US '426, motivated by the teaching of US '426 that the cells delivery allows implantation of artificial organs, with reasonable expectation of the delivered structure to deliver cells at the site of insertion to allow implantation of organs as possible and needed.

10. Claims 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '593 in view of US 4,104,195 ('195).

US '593 discloses bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The fibers can also comprise titanium, metal alloys such as chromium, cobalt, and

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molybdenum (col.19, lines 40-45). The fibers of the invention are form solid form by melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48; col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26).

The reference does not teach the particular foam forming agents. The reference does not teach the partial coating of the core.

The partial coating of the device is within the skill in the art depending on particular use.

US '195 teaches foam forming agents that does not give off any corrosive, discoloring, unpleasant smelling or toxic decomposition products (col.1, lines 52-57). The foam forming agents disclosed by the reference include azodicarbonamide and urea dicarboxylic acid anhydride (col.2, lines 47-60).

It is also within the skill in the art to select the foaming material according to specific need, especially applicants provided no unexpected result to show the criticality of the azodicarbonamide and urea dicarboxylic acid anhydride as foaming agents.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide biocompatible biodegradable filament comprising core-sheath structure as disclosed by method disclosed by US '593, and replace the chemical foaming agent disclosed by US '593 by the azodicarbonamide or urea dicarboxylic acid anhydride as disclosed by US '195 motivated by the teaching of US '195 that these agents do not give off any corrosive, discoloring, unpleasant smelling or



toxic decomposition products, with reasonable expectation of having filaments suitable for implantation into a needy host.

***Response to Declaration***

11. The declaration under 37 CFR 1.132 filed 01/02/2004 has considered, but is not pertinent to the new ground of rejection.

***Claim Objections***

12. Claims 7-10 are objected to as being dependent upon a rejected base claim, but would be allowable if their limitation are incorporated in the independent claim as part of the claimed structure, and not as an intended function of the structure, and rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claim 37 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

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**ISIS GHALI**  
**PATENT EXAMINER**

